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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/850,091 | 05/08/2001 | Etsuko Matsunaga | 206445US0CONT | 1424 |

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ALEXANDRIA, VA 22314

EXAMINER

IBRAHIM, MEDINA AHMED

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

12

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/850,091

Applicant(s)
MATSUNAGA et al

Examiner
Medina Ibrahim

Art Unit
1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 25, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, and 11-24 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 9, 10, 25, and 26 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Applicant's response filed 03/25/03 in reply to the Office action mailed 9/25/02 and amendment B have been entered. The IDS of 03/025/03 has been considered.

Claims 1-26 are pending and are under examination.

All previous rejections and objections not stated below have been withdrawn.

This Office action contains NEW GROUNDS OF REJECTION not necessitated by Applicants' amendments. Therefore, this action is non-final. The delay in applying these new grounds of rejection is regretted.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-8 and 11-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of introducing a gene into a plant comprising introducing into a plant a vector comprising the cytokinin-related gene of CKI1 as a selectable marker gene under the control of a light inducible promoter, and a removable DNA, transformed plant cell and plant produced by said method, and the vector, does not reasonably provide enablement for a method that employs any adventitious shoot redifferentiation gene to improve redifferentiation efficiency of a transgenic tissue and transgenic plant and plant cell produced by said method. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. .

The claims are broadly drawn to a method for introducing a gene into a plant , comprising introducing a vector comprising an adventitious shoot redifferentiation gene as a selectable marker gene under the control of a light inducible promoter, a removable DNA element, wherein the selectable marker gene, and not the desired gene, is positioned such that it behaves integrally with the removable DNA, and transgenic plant and plant cells produced by said method. The claims also encompass the cytokinin-related gene of CK11 as a selectable marker and specific removable DNA element and a method for improving redifferentiation efficiency of a transgenic tissue by using said vector. .

Applicant provides guidance for a vector plasmid comprising the ipt gene as a selectable marker under the control of rbcS-P gene promoter (Figure 2), and a method of transforming plant cells with said plasmid vector, wherein the plant cell expressing the ipt form tissue having abnormal morphology or an extreme shooty phenotype can be easily selected (Example 1-3). Applicant teach that when ipt gene is used as a selectable marker under a light inducible promoter, the gene introduction efficiency, selection efficiency of transgenic tissues, and the ratio of the transgenic tissues in the redifferentiated adventitious shoots were higher when the ipt gene is expressed under CaMV 35 S promoter or under native promoter (Table 1, page 42). Applicants show that by using a vector comprising an ipt gene as a selectable marker under the light

inducible promoter, and a removable DNA, a desired gene can be introduced into plant. And by the action of the removable DNA, the selectable marker losses its function and moves out together with the removable DNA from the introduced genome, and as a result the desired gene alone remains in the transformed plant genome (Example 4, I-II).

Applicant has not provided guidance for other adventitious shoot redifferentiation genes which can be used as selectable marker genes, so that a gene introduction efficiency can be achieved in any transgenic plant or plant part. The specification, page 12, lines 3-7, states "that the ipt gene encodes an easily selectable altered morphology, and it is unclear whether other genes even if available would provide transformant selection based on morphology and/or gene introduction efficiency.

The state of the art as evidenced by Walden et al (Eur. J. Biochem, vol 192, pp. 563-576, 1990) teach that not all selectable markers function uniformly in all plant species (page 563, column 2, under "Genetic Markers for use in plant cells"). The cited reference states "(hence) markers required for dominant selection may differ between not only different plant species but also different cell types within an individual". Given the claim breadth, the state of the art and the unpredictability inherent in selectable markers as evidenced by Walden, and lack of guidance as discussed above, the claimed invention is not enabled throughout the broad scope.

Remarks

Claims 4-5, 9-10 and 25-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

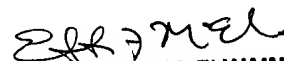
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

May 29, 2003

mai


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800